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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,697	04/05/2002	Akane Takemura	011633	3246
23850 7590 09/15/2009 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005				
EXAMINER PORTER, RACHEL L				
ART UNIT		PAPER NUMBER		
3626				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/926,697

**Applicant(s)**

TAKEMURA ET AL.

**Examiner**

RACHEL L. PORTER

**Art Unit**

3626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 47, 51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47, 51-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the amendment filed 6/11/09. Claims 47, 51-52 are pending.

***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/11/09 has been entered.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 47, and 51-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, claim 47 recites a "risk improvement sheet," but it is unclear which form the recited sheet takes. In other words, as described in the on page 18, lines 8-21

of the specification, the risk improvement table is described in a plurality of embodiments. These include a paper medium, or table display realized using a computer program. At present, the claim language recites "a risk estimation part" and "a risk avoidance measure presentation part."

However, if applicants intends to claim merely a sheet (e.g. a paper medium), is unclear how portions of a page or any display item alone can function in the recited capacities. It is noted that the claim has been amended. However, the claim amendment fails to clarify the claim issues.

For the purpose of applying art, the examiner will interpret the claim language and the recited sheet to be any printed medium.

Claims 51 and 52 inherit the deficiencies of claim 47 through dependency and are therefore also rejected.

The claim limitations "examination means for implementing a question-based examination..." and "calculating means for applying examination results to the risk estimation part ..." in claim 52 use the phrase "means for" or "step for", but it is modified by some structure, material, or acts recited in the claim. It is unclear whether the recited structure, material, or acts are sufficient for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph, because is unclear how portions of a page alone can function in the recited capacities (examination or calculations).

If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that the phrase “means for” or “step for” is clearly **not** modified by sufficient structure, material, or acts for performing the claimed function.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that it will clearly not be a means (or step) plus function limitation (e.g., deleting the phrase “means for” or “step for”).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Dewey et al (US 5,084,819).

[claim 47] Dewey discloses a disease risk improvement sheet, said sheet including a surface (e.g. Figure 3) further comprising a risk estimation part and a risk avoidance measure presentation processing part, wherein said risk estimation processing part has:

- a data gathering part that displays a current absence/presence plurality of risk factors, and an answers section corresponding to the examination item display section; (Figure 3 (answers) ; Tables 1,5—solicits users for questions and answers are shown)

- a judgment criteria part that stipulates an unequivocal correlation between the answers and preset risk values; (Tables 5- assigns weights to answers and determines a score; (see also table 4 which includes criteria))
- a risk judgment part provided with a judgment section for recording the risk values for the risk factors converted from the answers of the answers section and space for calculating an overall risk value by arithmetic; and (Tables 1,5 (see also table 4 which includes criteria))
- an overall risk display part provided with an overall risk judgment criteria section that unequivocally stipulates an overall risk allocated to one of a plurality of preset levels from the overall risk value, the overall risk display section that displays an overall risk showing a risk level of an examinee, and an explanation section that explains the risk level and, (Table 5 –summarizes weighted answers, gives risks and scores)
- wherein said risk avoidance measure presentation part includes
  - a risk avoidance measure display part in which are shown a necessity of re-examination and a time of re-examination (Tables 5; col. 7, lines 64-col. 8, line 10) , a guidance display section in which are displayed guidance contents for guiding lifestyle so as to reduce the risk, (Table 5) and a means display section in which are display tools for carrying out the risk improvement in accordance with a guidance of said display section; and (Table 5)
  - an improvement possibility display part. (Table 5)

Regarding the description of the risk improvement sheet as an “oral disease” risk

improvement sheet and the description of the segments of the risk improvement sheet, it should also be noted that the details regarding the contents and parts of the "oral disease" risk improvement sheet are non-functional descriptive material. No patentable weight is given to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d 1035; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dewey in view of Connelly (US 5,738,113)

[Claim 51] Dewey discloses an oral disease risk improvement sheet recited in claim 47 as explained in the rejection of claim 47.

Dewey does not expressly disclose providing a risk improvement tools including guidance tools comprising any one of videos, CDs, cassette tapes, panels, books, computer software containing guidance on improving eating habits and brushing guidance used for the purpose of teaching knowledge and increasing awareness with regard to oral hygiene, diseases, or products for the oral cavity comprising any one of

the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators.

Connelly discloses providing risk improvement tools to patients including products (e.g. panels-home instructions) for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators. (Col. 9, lines 55-65; col. 10, lines 1-60, Table 4; e.g. panels-home instruction kits). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Dewey with the teaching of Connelly to include panels/products to prevent or reduce disease risk. As suggested by Connelly, one would have been motivated to include these features to provide cost-effective, inexpensive interventions which require minimal dental infrastructure (col. 2, lines 25-29)

[Claim 52] Dewey discloses an oral disease risk improvement sheet recited in claim 47 as explained in the rejection of claim 47.

- examination means for implementing a question-based examination and an oral cavity examination as indicated by said risk improvement table on each test subject; (Figure 3, Table 1—"as indicated by said risk improvement table" is question and answer inventory)
- calculating means for applying examination results to the risk estimation part of said risk improvement table, working out a risk value for each risk factor judged objectively, and calculating an overall risk value; and (Tables 4-5)



Dewey does not expressly disclose providing a risk improvement tools including guidance tools comprising any one of videos, CDs, cassette tapes, panels, books, computer software containing guidance on improving eating habits and brushing guidance used for the purpose of teaching knowledge and increasing awareness with regard to oral hygiene, diseases, or products for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators.

Connelly discloses providing risk improvement tools to patients including products (e.g. panels-home instructions) for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators. (Col. 9, lines 55-65; col. 10, lines 1-60, Table 4; e.g. panels-home instruction kits). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Dewey with the teaching of Connelly to include panels/products to prevent or reduce disease risk. As suggested by Connelly, one would have been motivated to include these features to provide cost-effective, inexpensive interventions which require minimal dental infrastructure (col. 2, lines 25-29)

### ***Response to Arguments***

9. Applicant's arguments filed 6/11/09 have been fully considered but they are not persuasive.

(A) Applicant argues that Dewey does not disclose all of the limitations of Claim 47, as amended.

In response, applicant's amendments still fail to overcome the rejection under Dewey.

Regarding the description of the risk improvement sheet as an "oral disease" risk improvement sheet and the description of the segments of the risk improvement sheet, it should also be noted that the details regarding the contents and parts of the "oral disease" risk improvement sheet are non-functional descriptive material. No patentable weight is given to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d 1035; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

(B) Applicant argues that Connelly does not disclose a sheet, as required by claims 51-52.

In response, claims 51-52 recite a risk care business system, which appears to include more than the sheet (e.g. risk improvement tools comprising any one of the items listed in claim 51). Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./  
Examiner, Art Unit 3626

/Robert Morgan/  
Primary Examiner, Art Unit 3626